



Food and Drug Administration
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June 23, 2015

Merits Health Products Co., Ltd.
Vincent Chen, Manager
No.18 Jingke Rd.
Nantun District
Taichung, 40852 Taiwan
R.O.C.

Re: K142912
Trade/Device Name: Merits Yoga Power Scooter, S542
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized Three-Wheeled Vehicle
Regulatory Class: Class II
Product Code: INI
Dated: May 26, 2015
Received: June 1, 2015

Dear Mr. Chen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142912

Device Name

Merits Yoga Power Scooter, S542

Indications for Use (Describe)

The Merits Yoga Power Scooter, S542, is to provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Merits Health Products Co., LTD.
510(k) Premarket Notification

Submitter:

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Date Prepared:

Dec. 18, 2014

Proprietary Name:

Merits Yoga Power Scooter, S542

Common name:

Three Wheel Power Scooter

Classification name:

Physical Medicine / Motorized Three – Wheeled Vehicle

Product Code:

INI

Regulation number:

890.3800

Comparison to Predicate Devices:

This submission indicates the Substantial Equivalence of the Merits Yoga Power Scooter, S542, with the predicate Travel Ease Electric Scooter, Model Pioneer 5 (K013788). S542 has the same intended uses and similar indications, technological characteristics and principles of operation with predicate device.

Device Description

The Merits Yoga Power Scooter, S542, is battery powered, rear transaxle driven and is controlled by the PG S-Drive 45amp controller. The user interface is a wig-wag control lever and a speed knob on the control panel. S542 is powered by one 12 VDC 11.5Ah battery. The batteries are charged by 4.3A off-board charger connect with 3-pin Microphone Connector to charging socket on the rear shroud. The approximate driving range on fully charged batteries is up to 18km (11.3mi). The scooter frame is a welded aluminum construction and includes 2 rear wheels with drive units (including motor, gear box, and brake), a removable battery pack, a front wheel set which consists of 2 wheels for better stability and a tiller to control its turning direction. When the user activates the wig-wag control lever, the controller receives a signal to release the brakes. With the brakes released, the scooter is allowed to move forwards or backwards. When the user releases the control lever, the scooter slows to a stop and the brakes are automatically re-engaged. The solenoid electromechanical brakes allow the user stop by letting go of the control lever. The frame is designed to be foldable for easy storage and transportation.

For safety reason, this solenoid electromechanical brake is designed as normal close type. In case of the brake or electrical failure, the brake shoe will re-engage automatically to prevent the movement of the scooter. The upholstery of the device complies with ISO 7176-16:2012 Resistance to ignition of postural support devices.

The device can be operated on dry, level surfaces composed of concrete, blacktop, or asphalt under normal driving conditions.

The Merits Yoga Power Scooter, S542, is substantially equivalent to the Merits Travel Ease Electric Scooter, Model Pioneer 5 (K013788). Both products are battery power, motorized vehicles designed for use as personal power mobility aids. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to provide outdoor and indoor mobility to persons limited to a seated position that are capable of operating a powered vehicle. Additional, they are all constructed from the same basic materials, have the same basic operational principles and all use DC batteries as their source of power.

Although there are some minor differences between S542 and its predicate device. But they raise no new issues of safety or effectiveness. Performance data demonstrate that S542 is safe. The non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

Intended Use

The Merits Yoga Power Scooter, S542, is to provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.

Discussion of Non-clinical Tests Performed for Determinations of Substantial equivalence are as follows:

ISO 7176-1:1999	Determination of Static Stability
ISO 7176-2:2001	Determination of Dynamic Stability of electric wheelchairs
ISO 7176-3:2012	Determination of effectiveness of brakes
ISO 7176-4:2008	Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5:2008	Determination of overall dimensions, mass and maneuvering space
ISO 7176-6:2001	Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-7:1998	Method of Measurement of Seating and Wheel Dimensions
ISO 7176-8:1998	Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9:2009	Climatic tests for wheelchairs
ISO 7176-10:2008	Determination of obstacle-climbing ability of electrically power wheelchairs
ISO 7176-11:2012	Test dummies
ISO 7176-13:1989	Determination of coefficient of friction of test surfaces
ISO 7176-14:2008	Power and control systems for electrically powered wheelchairs and scooter- Requirements and test methods.
ISO 7176-15:1996	Requirements for Information Disclosure, Documentation and Labeling
ISO 7176-16:2012	Resistance to ignition of postural support devices
ISO 7176-21:2009	requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.
ISO 14971:2007	Medical devices -- Application of risk management to medical devices

The results of the testing confirm that the device meets specifications and is substantially equivalent to the predicate device.

Substantial Equivalence Discussion

The Merits S542 Scooter is substantially equivalent to the Merits Travel Ease Electric Scooter, Model Pioneer 5 (K013788). Both products are battery power, motorized, seating systems designed for use with electric scooters. Performance characteristics and drive mechanisms are similar and all have the same intended function and use which is to provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls. Additional, they are all constructed from the same basic materials, have the same basic operational principles and all use DC batteries as their source of power. The comparison table is as follow:

Characteristics		Merits Yoga Power Scooter, S542	Merits Travel Ease Electric Scooter, Model Pioneer 5
Intended Use		To provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.	To provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.
Dimension	Length	39" (±0.6") / 20.2" (±0.6")	38.5"
	Width	17.2" (±0.6")	19.7"
	Height	39.6" (±0.6") / 24.2" (±0.6")	48"
Weight	Total	56.7 lb	92 lb
	Base	53 lb (Seat Not Removable)	50 lb
	Seat		19 lb
	Battery	3.7lb	23lb
Seat Height (From Deck)		15.6"	16"
Seat Width		14.2"	14"
Seat Depth		12.4"	12.5"
Armrest Type		Removable & Flip Backward	Removable & Flip Backward
Weight Capacity		250 lb	250 lb
Gradient		6°	6°
Turning Radius		37.8"	33.8"
Ground Clearance		3.7"	2.4"
Tires		Front: 6"/ Rear: 7" (PU Tires)	Front: 8"/ Rear: 8" (PU Tires)
Suspension		Front Wheel Leaf Spring	No Suspension
Max. Speed		4 mph	4.5 mph
Range up to		11.25 miles	10 miles
Power		24V/11.5Ah Li-ion Battery	24V/12Ah Lead Acid Battery

There are some difference between S542 and its predicate device raise:

- Turning Radius: The device passed ISO 7176-2:2001(Determination of Dynamic Stability of electric wheelchairs): Item 10.3 and 10.4. So there is no deleterious affection of safety and effectiveness about the difference on Turning Radius with predicated device.
- Dimension: The device passed ISO 7176-1:1999 (Determination of Static Stability) and ISO 7176-2:2001(Determination of Dynamic Stability of electric wheelchairs). So there is no deleterious affection of safety and effectiveness about the difference on Dimension with predicated device.
- Range up to: The travel range of S542 is better than the predicated device.
- Max. Speed: The device has passed ISO 7176-2:2001(Determination of Dynamic Stability of electric wheelchairs) & ISO 7176-8 (Requirements and test methods for static, impact and fatigue strengths) test (Please see Appendix IV: Test reports). So there is no deleterious affection of safety and

effectiveness about the difference on Max. Speed with predicated device.

- e. Weight: Although the total weight of S542 is lighter than Merits Travel Ease Electric Scooter, Model Pioneer 5 (K013788). The device has passed ISO 7176-8 (Requirements and test methods for static, impact and fatigue strengths) test (Please see Appendix IV: Test reports). So there is no deleterious affection of safety and effectiveness about the difference on Weight with predicated device. As the S542 is lighter than the predicate device, it is more suitable for user to carry and transport by vehicles.
- f. Battery: The S542 is using Li-ion Battery. It is lighter than the conventional Lead Acid Batteries. Although the capacity of the new battery is slightly smaller than the predicated device. Its travel range is longer than the predicated device. The device has passed ISO 7176-8 (Requirements and test methods for static, impact and fatigue strengths) test (Please see Appendix IV: Test reports). And the Li-ion Battery has passed the UN 38.3 Transportation Testing Required for Lithium Battery Safety during Shipping to ensure its safety. (Please see Appendix X: Part I Test reports). So there is no deleterious affection of safety and effectiveness about the difference on Battery with predicated device.
- g. The seat height, width and depth for both devices are almost the same. They are all equipped with Removable and Flip Backward Armrest for users to leave the seats easily and more compact for storage.

The front wheel set of S542 is equipped with a leaf spring suspension. This makes the S542 more comfortable than the predicated device. The device has passed ISO 7176-2:2001(Determination of Dynamic Stability of electric wheelchairs) & ISO 7176-8 (Requirements and test methods for static, impact and fatigue strengths) test (Please see Appendix IV: Test reports). So there is no deleterious affection of safety and effectiveness about the difference on this suspension with the predicated device.

Conclusions

According to comparison table and discussions above, the differences on total weight, speed, battery size, suspension type and dimensions do not deleteriously affect the safety and effectiveness of the device.

So based on the design, performance specifications and testing and intended use, the Merits Yoga Power Scooter, S542, is substantially equivalent to the Merits Travel Ease Electric Scooter, Model Pioneer 5 (K013788).